

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :
Yohko AKIYAMA et al. : **Mail Stop: PCT**
Serial No. NEW : Attorney Docket No. 2005_0380A
Filed March 8, 2005 :

SUSTAINED-RELEASE PREPARATION
[Corresponding to PCT/2003/011570
Filed September 10, 2003]

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☒ each U.S. Patent and U.S. Patent application publication;
- ☒ each reference previously cited in the international application PCT/2003/011570; and/or
- ☐ each reference previously cited in prior parent application Serial No. _____.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, **or**

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

and thus no certification and/or fee is required.

- 1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

- (1) ☐ the certification of paragraph 2 below is provided, **or**
(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

- 1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

**the certification of paragraph 2 below is provided, and
the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

2. It is hereby certified

- a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ a full or partial English language translation submitted herewith,
 - b. ☒ a foreign patent office search report (in the English language) submitted herewith,
 - c. ☐ the concise explanation contained in the specification of the present application at page,
 - d. ☐ the concise explanation set forth in the attached English language abstract,
 - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☒ A foreign patent office search report citing one or more of the references is enclosed.

Respectfully submitted,

Yohko AKIYAMA et al.

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March 8, 2005

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)

Date Submitted to PTO: March 8, 2005

ATTY DOCKET NO.
2005_0380ASERIAL NO.
NEW 10/526792APPLICANT
Yohko AKIYAMA et al.FILING DATE
March 8, 2005

GROUP

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	2002/0049164	4/2002	Dumuth et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
	AB	02/062764	8/2002	WO			
	AC	01/72290	10/2001	WO			
	AD	01/22941	4/2001	WO			
	AE	00/21525	4/2000	WO			
	AF	99/58114	11/1999	WO			Abstract
	AG	0 284 849	10/1988	EP			
	AH	01/47557	7/2001	WO			Abstract
	AI	2002-179554	6/2002	JP			Abstract
	AJ	1 110 541	6/2001	EP			
	AK	01/55105	8/2001	WO			
	AL	02/02560	1/2002	WO			

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

AM	J.A. Pospisilik et al., "Long-Term treatment with the Dipeptidyl Peptidase IV Inhibitor P32/98 causes Sustained Improvement in Glucose Tolerance, Insulin Sensitivity, Hyperinsulinemia, and β -Cell Glucose Responsiveness in VDF (fa/fa) Zucker Rats", Diabetes, Vol. 51, No. 4, April 2002, pp. 943-950.
AN	K. F. Mace et al., "The Pharmacokinetics of LY307161 SR, a sustained release formulation of a DPP-IV resistant GLP-1 analog, administered by subcutaneous injection in rats and dogs", Diabetol. Ogia., Vol. 45, No. 2, August 2002, pp. A176.
AO	R.A. Byrd et al., "Reproductive and developmental toxicity studies in rats and rabbits with LY307161 SR, a sustained-release formulation of a Dipeptidyl Peptidase-IV (DPP-IV) resistant glucagon-like peptide 1 (GLP-1) analog", Analog. Teratology, Vol. 65, No. 6, June 2002, pp. 339.

EXAMINER /Paul Dickinson/

DATE CONSIDERED 05/11/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.D./